ELEVEN BLADE SOLUTIONS

JAN 9 2013

510(k) Summary

General Company Information		
Name:	Eleven Blade Solutions, Inc.	
Contact:	Michael Kolber Regulatory Affairs	
Address:	147 Hillbrook Dr. Los Gatos, CA 95032	
Telephone:	408-505-6626	
Fax:	408-402-8361	
Date Prepared:	January 7, 2013	
General Device Information		
Product Name:	Q-Fix™ Suture Anchor System	
Common Name:	Suture Anchor	
Classification:	21CFR888.3040; Smooth or threaded metallic bone fixation fastener	
Device Class:	Class II	
Product Code:	MBI	
Predicate Devices		
Manufacturer	Device Name	510(k) Number
Biomet Sports Medicine	Juggerknot Soft Anchor	K110145
Teleflex Medical	ForceFiber	K063778

Description

The Q-Fix™ Suture Anchor is an all-suture anchor device designed for soft tissue to bone fixation by expanding against bone when deployed. Made of a polyester sleeve-type structure with one or more strands of UHMWPE suture threaded through it, the anchor is provided preloaded on a disposable inserter. The inserter is used to deploy the anchor into the bone, with the suture remaining slideable within the anchor to facilitate attachment of the soft tissue.

The one-time use anchor is provided sterile, preloaded on the inserter. Additional accessory instruments, including a drill bit and drill guide with obturator are single use devices provided sterile for use during the orthopedic procedure.

Intended Use (Indications)

The Eleven Blade Solutions, Inc. Q-Fix™ Suture Anchor System is intended for soft tissue to bone fixation for:

Shoulder

Bankart lesion repair, SLAP lesion repair, Acromio-clavicular repair, Capsular shift/capsulolabral reconstruction, Deltoid repair, Rotator cuff repair, Biceps tenodesis

Foot and Ankle

Medial/lateral repair and reconstruction, Mid and forefoot repair, Hallux valgus

reconstruction, Metatarsal ligament/tendon repair or reconstruction, Achilles tendon repair

Elbow
Ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair, Biceps tendon reattachment

Knee
Extra-capsular repair: MCL, LCL, and posterior oblique ligament, Illiotibial band tenodesis, Patellar tendon repair, VMO advancement, Joint capsule closure

Hand and Wrist
Collateral ligament repair, Sacpholunate ligament reconstruction, Tendon transfers in phalanx, Volar plate reconstruction

Hip
Acetabular labral repair

Substantial Equivalence

This submission supports the position that the Eleven Blade Solutions, Inc. Q-Fix™ Suture Anchor System is substantially equivalent to the Biomet Juggerknot (K110145) and the Teleflex ForceFiber (K063778). The Q-Fix™ Suture Anchor System has the following similarities to the previously cleared predicate device: the same intended use, same operating principle, similar technologies, and similar manufacturing process. Design verification activities were performed as a result of the risk analysis. The 510(k) notice contains summaries of bench studies, which were conducted to evaluate the performance characteristics of the Q-Fix™ Suture Anchor System. Anchor Pull-out Strength, Cyclic Displacement, and Device Insertion Testing were performed. The data presented demonstrate that the performance characteristics of the Q-Fix™ Suture Anchor System are equivalent to the predicate devices and thus provide equivalent fixation strength within their intended use.

Conclusions

Eleven Blade Solutions, Inc. believes that the information provided demonstrates that the proposed device is substantially equivalent to the predicate devices and does not raise any new issues of safety or efficacy. Based on the indications for use, technological characteristics, and comparison to predicated devices, the Q-Fix™ Suture Anchor System has been shown to be substantially equivalent to predicate devices as described under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Eleven Blade Solutions, Incorporated
% Mr. Michael Kolber
Regulatory Affairs
147 Hillbrook Drive
Los Gatos, California 95032

Letter dated: January 9, 2013

Re: K122336
Trade/Device Name: Eleven Blade Solutions, Incorporated. Q-Fix™ Suture Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener.
Regulatory Class: Class II
Product Code: MBI
Dated: November 23, 2012
Received: November 26, 2012

Dear Mr. Kolber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122336

Device Name: Eleven Blade Solutions, Inc. Q-Fix™ Suture Anchor System

Indications for Use: The Eleven Blade Solutions, Inc., Q-Fix™ Suture Anchor System is intended to be used for soft tissue to bone fixation for:

Shoulder
Bankart lesion repair, SLAP lesion repair, Acromio-clavicular repair, Capsular shift/capsulolabral reconstruction, Deltoid repair, Rotator cuff tear repair, Biceps tenodesis

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Hip
Acetabular labral repair

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices
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